

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

AMINOPHYLLINE 250 mg IV FRESENIUS solution for injection

Aminophylline dihydrate

Sugar free

Read all of this leaflet carefully before AMINOPHYLLINE 250 mg IV FRESENIUS is administered:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What AMINOPHYLLINE 250 mg IV FRESENIUS is and what it is used for
2. What you need to know before AMINOPHYLLINE 250 mg IV FRESENIUS is administered
3. How AMINOPHYLLINE 250 mg IV FRESENIUS will be administered
4. Possible side effects
5. How to store AMINOPHYLLINE 250 mg IV FRESENIUS
6. Contents of the pack and other information.

1. What AMINOPHYLLINE 250 mg IV FRESENIUS is and what it is used for

AMINOPHYLLINE 250 mg IV FRESENIUS belongs to a group of medicines known as xanthines.

It is used to treat breathing difficulties associated with reversible airway obstruction, as in acute asthma, chronic bronchitis (persistent coughing which can make it difficult to breath) and emphysema (a condition in which the air sacs of your lungs are damaged and enlarged, causing breathlessness).

2. What you need to know before AMINOPHYLLINE 250 mg IV FRESENIUS is administered

AMINOPHYLLINE 250 mg IV FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to aminophylline dihydrate or any of the other ingredients of AMINOPHYLLINE 250 mg IV FRESENIUS (listed in section 6)
- if you are hypersensitive (allergic) to theophyllines (used to treat wheezing, shortness of breath, and chest tightness), caffeine (used to improve mental alertness) or theobromine (used as a vasodilator, a blood vessel widener)
- if you have porphyria (a condition that affects your blood)
- if you have an active ulcer in your stomach or lining of your stomach, small intestine or oesophagus.
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Warnings and precautions

Take special care with AMINOPHYLLINE 250 mg IV FRESENIUS:

- if you have epilepsy
- if you are a smoker or if you start or stop smoking while being treated with AMINOPHYLLINE 250 mg IV FRESENIUS
- if you have a virus infection, such as flu, or if you have recently received a flu injection
- if you have liver or kidney problems

- if you have heart problems
- if you have problems with your lungs
- if you are an alcoholic
- if you are a male over 55 years old with lung problems
- if you have a bacterial blood infection
- if you have high blood pressure
- if you have an overactive thyroid (the thyroid gland produces too much thyroid hormone which increases your body's metabolism)
- if you have a history of ulcers in the lining of your stomach, small intestine or oesophagus
- if you have an eye condition called glaucoma (high pressure in your eye(s))
- if you are a diabetic (high blood sugar levels)
- if you have low blood oxygen levels (shortness of breath, bluish colour in the skin, fingernails, and lips).

Other medicines and AMINOPHYLLINE 250 mg IV FRESENIUS:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently taking or receiving any of the following:

- alcohol
- aminoglutethimide (used to treat conditions which cause the body to make too much of certain hormones (Cushing's syndrome))
- barbiturates (used to treat sleeping disorders)
- rifampicin, isoniazid (used to treat tuberculosis (TB))
- phenytoin, carbamazepine, phenobarbitone, primidone (used to treat epilepsy)
- ritonavir (used in the treatment of HIV (human immunodeficiency virus) and AIDS (acquired immune deficiency syndrome))

- sulphinyprazone, allopurinol (used to treat gout)
- meprobamate, benzodiazepines, chlordiazepoxide (used to treat anxiety disorders)
- moricizine, cardiac glycosides (used to treat irregular heartbeats and to maintain a normal heart rate)
- intravenous isoproterenol (used to treat a slow heart rate)
- beta-blockers (propranolol), calcium channel blockers (used to treat high blood pressure)
- tacrine (used to treat Alzheimer's disease)
- fluvoxamine (used to treat obsessive-compulsive disorder (OCD))
- cimetidine, ranitidine (used to treat heartburn)
- macrolide antibiotics (erythromycin, lincomycin, clindamycin, clarithromycin, troleandomycin), tetracyclines (used to treat bacterial infections)
- fluoroquinolone and quinolone antibiotics (ciprofloxacin, ofloxacin, norfloxacin, enoxacin, penfloxacin) (used to treat bacterial infections)
- fluconazole (used to treat a fungal infection)
- thiabendazole (used to treat infections caused by worms, such as threadworm)
- interferon alfa (used to treat various cancers)
- influenza vaccine (used to prevent infection and severe outcomes caused by influenza viruses)
- disulfiram (used to treat chronic alcoholism)
- viloxazine, lithium (used to treat depression)
- mexiletine, propafenone (used to treat heart rhythm disorders)
- oral contraceptives, oestrogen-containing contraceptives (used to prevent pregnancy or to regulate your menstrual cycle)
- pentoxifylline, ticlopidine (used to improve blood flow)
- diltiazem, verapamil (used to treat high blood pressure and angina (chest pain))
- methotrexate (used to treat cancer, psoriasis (skin disorder that causes the skin cells to multiply up to 10 times faster) and rheumatoid arthritis (inflammation in the joints))
- zafirlukast (used to prevent asthma symptoms)
- thyroid hormones (help to regulate growth and metabolism)

- St. John's wort (*Hypericum perforatum*) (herbal medicine that may assist with depression, anxiety and sleep disorders)
- theophylline (used to treat symptoms associated with long term asthma)
- halothane, ketamine (used for induction and maintenance of general anaesthesia)
- pancuronium (used to provide skeletal muscle relaxation during surgery)
- furosemide (assist the body to get rid of extra water and salt)
- beta₂-adrenergic agonists (used to treat asthma and other disorders, such as chronic obstructive pulmonary disease (COPD))
- adenosine (used to treat surgical pain and nerve pain)
- doxapram (used to treat breathing problems due to overdose of certain medicines or lung disease).

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before AMINOPHYLLINE 250 mg IV FRESENIUS is administered.

The safety of AMINOPHYLLINE 250 mg IV FRESENIUS during pregnancy and breastfeeding has not been established.

Driving and using machines:

AMINOPHYLLINE 250 mg IV FRESENIUS can cause side effects, such as visual disturbances or vertigo (see 4. Possible side effects). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how AMINOPHYLLINE 250 mg IV FRESENIUS affects you.

3. How AMINOPHYLLINE 250 mg IV FRESENIUS will be administered

You will not be expected to administer AMINOPHYLLINE 250 mg IV FRESENIUS to yourself.

Your doctor or health care professional will administer AMINOPHYLLINE 250 mg IV FRESENIUS to you in the hospital.

Your dose will be determined by your doctor based on your weight. AMINOPHYLLINE 250 mg IV FRESENIUS will be given over a period.

If you have the impression that the effect of AMINOPHYLLINE 250 mg IV FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If more AMINOPHYLLINE 250 mg IV FRESENIUS is administered to you than should be:

Since a health care provider will administer AMINOPHYLLINE 250 mg IV FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

You may experience the following symptoms in the event of an overdosage: nausea (feeling sick), vomiting (being sick), vomiting of blood, runny/loose stool, restlessness, irritability, headache, extreme thirst, slight fever, seeing things that are not real (hallucinations), convulsions (fits), changes in the way your heart beats (beating faster or slower or skipping beats).

If you missed a dose of AMINOPHYLLINE 250 mg IV FRESENIUS:

Since a health care provider will administer AMINOPHYLLINE 250 mg IV FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

AMINOPHYLLINE 250 mg IV FRESENIUS can have side effects.

Not all side effects reported for AMINOPHYLLINE 250 mg IV FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while

AMINOPHYLLINE 250 mg IV FRESENIUS is administered or after administration, please consult your health care provider for advice.

If any of the following happens, while AMINOPHYLLINE 250 mg IV FRESENIUS is being administered or after administration, tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AMINOPHYLLINE 250 mg IV FRESENIUS. You may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent:

- vomiting blood, dark or red blood mixed with your stool
- convulsions (fits).

Frequency unknown:

- more urine than is normal for you
- changes in the way your heart beats, for example, if you notice it beating faster or slower or skipping beats
- yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- headache, dizziness, vertigo (sensation of spinning or swaying)
- tremors (involuntary trembling or shaking of hands and feet)
- feeling irritable, restless, nervous
- difficulty falling asleep
- nausea, vomiting, heartburn, stomach pain.

Less frequent:

- diarrhoea.

Frequency unknown:

- low blood pressure
- excessive thirst, dry mouth and skin
- feeling dizzy, lightheaded or tired
- abnormally high body temperature with symptoms such as excessive sweating, flushed or red skin, muscle cramps, spasm, and pain
- feeling depressed, anxious
- visual disturbances.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via the **6.04 Adverse Drug**

Reaction Reporting Form, found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of AMINOPHYLLINE 250 mg IV FRESENIUS.

Health care providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store AMINOPHYLLINE 250 mg IV FRESENIUS

- Store at or below 30 °C.
- Protect from light.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What AMINOPHYLLINE 250 mg IV FRESENIUS contains:

Each 10 ml contains 250 mg aminophylline dihydrate equivalent to 230 mg aminophylline (anhydrous).

The other ingredients are ethylenediamine and water for injection.

What AMINOPHYLLINE 250 mg IV FRESENIUS looks like and contents of the pack:

Clear colourless to pale yellow solution in ampoules.

10 ml amber ampoules, 10's or 100's.

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

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